All glassware will be rinsed by the analyst after its use and before being placed in the glassware washing areas. There should be a double rinse with the last solvent contained by that piece of glassware. Glassware containing chemicals, reagents, or samples will not be left so that these materials become dried onto the surface.
Glassware is cleaned using Liquinox and/or Detergent 8 when washed by hand. Glassware washed using the laboratory dishwasher is cleaned using NeoDisher LaboClean FLA and NeoDisher 2. Glassware is inspected prior to use. If it is not clean, it is not used. Glassware that can not be cleaned is discarded to prevent possible contamination of sample analysis.

Volumetric Dispensing Devices (auto-pipettes)

Auto-pipettes are checked for precision and accuracy initially, and quarterly thereafter by weighing ten replicate measurements of water, calculating the volume of each, and determining standard deviation and percent accuracy. The relative standard deviation must be ≤ 1 and accuracy must be +/- 2% of the nominal volume.

Auto-pipettes that do not meet the requirements stated above are removed from service and cleaned, repaired or discarded.

SECTION 8: Sample Collection

Monitoring Well Sampling:

All monitoring well samples will be collected according to EPA guidelines (EPA Report No. 600/4-82-029, The Handbook for Sampling and Sample Preservation of Water and Wastewater and USEPA Ground Water Issue Document EPA/540/S-95/504, April 1996, Low-Flow (Minimal Drawdown) Ground-Water Sampling Procedures.). Submersible sampling pumps, deep well jet pumps, or hand bailers will be used as necessary; however, no sample will be collected until the monitoring well has been evacuated to five (5) times the volume of water that is standing in the casing or when stabilization readings indicate a stable aquifer.

Composite Wastewater Sampling:

All composite wastewater samples will be collected according to EPA guidelines (EPA Report No. 600/4-82-029, The Handbook for Sampling and Sample Preservation of Water and Wastewater). Automatic interval sampling devices will be used where allowable.

Drum Sampling:

Drum samples are obtained by the use of a coliwassa sampler or other type of drum thief, which retrieves a cross-section of the entire drum.

Wipe Sampling:

Wipe samples are recommended for non-porous surfaces only. The area to be sampled is marked by the use of a disposal template, usually at least 100 square centimeters in area. The area within the template is wiped with a 2 by 2-inch sterile gauze pad or a piece of filter paper moistened with the appropriate reagent.

PCB Wipe Sampling:

To sample and test for PCBs, a gauze pad is moistened with hexane, wiped across the proposed area, then placed in a 4-oz. glass container with a Teflon-lined lid. The bottle is then labeled completely with the client sample ID, and the time and date of the sampling event. Nitrile gloves are used to hold the gauze during sampling and are disposed of after each sample to avoid cross-contamination.

Metals Wipe Sampling:

Wipe sampling to test for metals follows the same procedures as above except using a pre-moistened Ghost Wipe.

Sampling for Low Level Metals Analysis

Sampling for Low Level metals analysis is performed according to the guidelines set forth in US EPA Method 1669: *Sampling Ambient Water for Trace Metals at EPA Water Quality Criteria.* This method requires the use of techniques designed to prevent contamination of samples by environmental factors, field technicians and other sources of contamination.

SECTION 9: Sample Receipt and Storage

How samples are delivered to TRACE

Samples can be delivered to the laboratory in several ways:

Client drop off:

Clients may drop off samples at the laboratory between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday. Holiday and Saturday deliveries are available if special arrangements have been made with the Project Manager.

Upon sample delivery, the client will be requested to initiate a TRACE Chain-of-Custody (C-O-C) record. The sample receiving department will document the apparent condition of samples on the C-O-C record (e.g., whether samples were refrigerated upon receipt, contained headspace, etc.) and complete the sample login checklist.

Samples should be kept on ice from the time sampled to delivery to the laboratory. Proper and full documentation is required, including the information found in the "Chain-of-Custody Documentation" section of this manual.

Commercial Delivery Service:

Samples may be sent to the laboratory by commercial carrier. It is important that the proper precautions are taken when sending via commercial delivery service:

- Sample temperatures must be kept between just above 0 and 6 °C.
- Make sure that coolers do not leak.
- Make sure that samples are shipped with the correct documentation and packaging, so that US DOT (US Department of Transportation), and the USDA (US Department of Agriculture) rules and regulations governing sample shipments are met.
- Call TRACE Analytical before shipping of any samples for Saturday or holiday delivery.

The sample receiving department will document the apparent condition of samples on the C-O-C record (*e.g.*, whether samples were refrigerated upon receipt, contained headspace, etc.) and complete the sample login checklist.

TRACE Analytical Laboratories, Inc., Courier Service:

TRACE is able to provide sample courier service to its clients. It is the courier's responsibility to collect all the pertinent paperwork from the client so that sample IDs, analyses requested, and sample preservation information will be readily apparent to laboratory personnel. The courier, upon return to the laboratory, will complete the C-O-C record to document the transfer of the samples.

The sample receiving department will document the apparent condition of samples on the C-O-C record (*e.g.*, whether samples were refrigerated upon receipt, contained headspace, etc.) and complete the sample login checklist.

TRACE Analytical Laboratories, Inc., Field Sampling Department:

It is the responsibility of the Field Sampling Department to properly label samples when collected and to initiate C-O-C records. Samples are to be placed in coolers packed with ice in order to bring the temperature to between just above 0 and 6° C as rapidly as possible.

Samples are to be kept on ice until delivery to the laboratory. Sample delivery should be accomplished as soon as possible.

Sample labels will contain the sample type, client name, site, sample identification, date and time of collection, preservatives used, test to be performed, and the name or initials of the person collecting the sample. This information must also be recorded on the C-O-C.

Upon delivery of samples to the laboratory, the field sampler transfers custody of the samples to the sample receiving department by completing the C-O-C.

The sample receiving department will document the apparent condition of samples on the C-O-C record (*e.g.*, whether samples were refrigerated upon receipt, contained headspace, etc.) and complete the sample login checklist.

Sample receiving by TRACE Analytical Laboratories, Inc.:

All samples received will be processed by the following procedures:

Chain-of-Custody Documentation:

The client or TRACE personnel will fill out a C-O-C record for all samples submitted to the laboratory. A copy of the completed C-O-C record will be given to the client while the original form will be placed in the client's project folder. The following information will be provided on the form:

- Sample identification names or numbers (*e.g.*, Well #1)
- Date and time of sample collection and analyses required for each sample
- Name of individual collecting samples and name of client submitting samples
- Address of client/telephone number/fax number/email address
- Client project number, where applicable
- TRACE quote number and/or client purchase order number
- Signature of individual delivering samples to the laboratory
- Signatures of any other individuals who took charge of the samples either during collection, transportation, or storage
- Date and time of delivery to the laboratory, signature of laboratory personnel accepting samples
- TRACE identification number
- Matrix and number of containers per sample
- Preservation and sample pH (where appropriate) and confirmation of field filtration
- Cooler temperature
- Turnaround time requested

Sample Login Checklist:

All coolers and samples will be checked using the Sample Login Checklist. Each cooler must have its own checklist. The following information is documented on this checklist:

Shipping Information

Date received
Client Name
Project Number
Project Name
TRACE personnel who logged in the submittal
Number of coolers
Cooler numbers
Bill of lading or tracking number
Use of custody seals
Type of packing used in the cooler

Method(s) of delivery

TRACE personnel
Client drop off
Commercial courier

Chain-of-Custody documentation

Sample condition
Appropriate paper work present
Special notations if needed

Coolant and Temperature documentation

The type of coolant used
Date and time the cooler temperature is taken.
Temperatures of temperature blank (if applicable)

Methanol Preserved Soil Samples:

Soil samples that are to be analyzed for Volatile Organic Compounds (VOCs) and are field preserved with methanol should be recorded on the Field Worksheet for Methanol Preserved Soils. This document must be sent to the laboratory.

For Methanol preserved samples that are shipped to TRACE:

The U.S. Department of Transportation, Title 49 of the Code of Federal Regulations regulates the shipping of methanol. The DOT number for methanol is: **UN 1230**. The amount of methanol used in sample preservation falls under the exemption for small quantities. The following requirements must be observed when shipping methanol preserved samples:

- The maximum amount of methanol per sample vial is to be no greater than 30 mls.
- The sample container cannot be completely filled with methanol.
- Each cooler may have no more than 500 mls of methanol
- Each cooler must be identified as containing less than 500 mls of methanol
- Each cooler must have a total weight of less than 64 pounds

Violations of the items listed above can result in fines or other punitive measures by the US Department of Transportation.

TRACE Identification Numbers:

Each new project will be assigned a TRACE project number upon entry into the Laboratory Information Management System (LIMS). This number will be entered on the client project folder, raw data sheets, C-O-C record, and on the individual sample bottle labels

Each individual sample will be given its own TRACE identification number.

Quality Control Check of Sample Receiving:

Each set of samples and the corresponding C-O-C and sample login checklist is double-checked by a second person to confirm that the login procedure is accurate. The second person will initial the C-O-C.

A new file folder will be obtained for each project and the following information will be recorded on the tab:

- Client name
- TRACE identification number
- File due date

File folders may be color coded to identify specific clients, analysis or turnaround times.

The TRACE identification number will be recorded on the C-O-C and entered into the LIMS system. It will be verified that the appropriate TRACE identification numbers have been recorded on the individual sample bottle labels and that all temperature-sensitive samples have been placed in the refrigerated storage room. All samples requiring volatile organic analysis are to be placed in segregated refrigerated storage.

Sample Custody, Security, Disposal and Subcontracted analysis:

Sample Custody:

It is important to minimize the number of people who physically handle samples in order to simplify record keeping. The traceability of sample custody is of vital importance for samples analyzed by TRACE Analytical Laboratories, Inc. According to the USEPA Contract Laboratory Program, Statement of Work, a sample is in your custody if:

- It is in your possession, or
- It is in your view after being in your possession, or
- It was in your possession and you locked it up, or
- It is in a designated secure area. (Secure areas shall be accessible only to authorized personnel)

All samples received by TRACE are maintained under custody at all times.

Sample Security:

All samples are stored in the laboratory, which is designated as a secure area. Security is maintained by locking all exterior entries into the laboratory and with keypad locks on all interior entryways.

No unauthorized personnel are allowed in the secure area unless escorted by authorized personnel. All non-TRACE employees are required to use the sign-in logbook (located in the lobby area) when entering and leaving the secured areas of the building.

Public areas at TRACE are designated as the front office areas, sample receiving and connecting hallways. These areas are accessible only during normal business hours.

Sample Disposal:

Samples are kept for a period of sixty (60) days after the final report for a project has been released. If samples are to be retained by TRACE for a longer period of time, then the client must indicate this when a project is initiated.

TRACE, in the disposal of samples, maintains documentation of disposal in LIMS. Manifests for the disposal of hazardous waste samples are maintained as well. At no time is client confidentiality to be compromised when samples are disposed.

Control of subcontracted analyses:

TRACE will occasionally utilize other laboratories for conducting specific analyses. These laboratories are selected on the basis of their ability to meet certain subcontract requirements, applicable certifications, establishment of a formal QA/QC program, and data integrity reputation.

Trace will inform clients when analyses are subcontracted to another laboratory. Trace will ensure that the subcontracted laboratory has any validations/certifications required by the client. Transfer of samples to a subcontract laboratory will be performed under a chain-of-custody. This information will be filed in the project file.

Trace is responsible to the client for the quality and timeliness of subcontracted work.

SECTION 10: Sample Container and Preservation

Sample Containers:

When collecting samples, the proper containers should be used to ship samples to the laboratory. Some environmental contaminates can interact with certain materials and compromise sample integrity. Data quality could be affected as well. In addition, the proper amount of sample needs to be collected in order to ensure that analyses can be performed correctly. Tables in Appendix II list the proper containers and sample amounts needed for analysis.

Sample Preservation:

Proper sample preservation is critical to maintaining sample integrity. Preservation should not be overlooked when collecting environmental samples. Samples that are not properly preserved will have data that are qualified. The tables in Appendix II give the proper preservation techniques for environmental analyses.

SECTION 11: Analytical Methods and Standard Operating Procedures

Analytical Methods:

When properly used, analytical methods should provide reliable information about the composition and nature of the sample being tested. In order for this information to be of value, the methods used should:

- Give evidence of the presence of the analyte
- Be able to separate the analyte from any interferences
- Be consistent with the level of analyte expected
- Be consistent with the sample matrix
- Have the required accuracy and precision
- Have the required lower limit of detection
- Be "rugged", *i.e.*, not sensitive to minor changes in variables, analysts, or laboratory
- Meet the regulatory requirements pertaining to the sample

Sources of Analytical Methods:

The methods used at TRACE are for the purpose of evaluating samples to determine their environmental significance, their potential impact on the health and well-being of individuals, or the operability or condition of equipment or a process. All of these purposes have the potential for significant economic or legal impact. Therefore, it is important to select published methods that have been widely tested, used and accepted. Wherever possible, the methods should be "standard" methods, *i.e.*, methods promulgated by a regulatory agency or other scientifically recognized organizations.

A list of the primary sources used for obtaining analytical methods employed at TRACE can be found in Appendix III.

A list of all methods under which Trace performs NELAC accredited analyses can be found in Appendix VII.

A list of the methods and Standard Operating Procedures (SOP's) used in the analysis of drinking water can be found in Appendix III.

Standard Operating Procedures:

TRACE develops in-house SOP's using the published methods as a reference. SOP's provide the analysts with detailed instruction on safety, sample preparation, analysis, quality control, and reporting. Any deviation from a SOP must first be approved by the Laboratory Area Manager and the QA/QC Manager.

SECTION 12: Data Validation, Reporting and Client Feedback

Routine Procedures for Data Validation:

All analytical data is thoroughly reviewed prior to report generation. The data review includes checks on data generation and reduction, and is performed as a three level review.

Level 1: Analyst Review

Level 1 is a technical data review performed by the analyst according to a prescribed set of guidelines. The review is designed to ensure the following:

- The sample preparation and analysis information are correct and complete
- The appropriate SOP's were followed
- The QC samples and blanks were analyzed and results are within established control limits
- The documentation is complete and any qualifications are recorded

Level 2: Technical Review

Level 2 is a technical review performed by the appropriate Laboratory Area Manager according to a prescribed set of guidelines. The review is designed to ensure the following:

- The appropriate SOP's were followed
- Calibration data is accurate and appropriate
- QC sample results are within established guidelines
- Qualitative identifications and quantitative results are correct
- Documentation is complete and the data is ready for incorporation into the final report

Level 3: Administrative Data Review

Level 3 is an administrative data review, which can be performed by the QA/QC Manager or the Laboratory Manager. The Level 3 review provides an overview of the entire data package. The review is designed to ensure the following:

- The completion and documentation of the Level 1 and 2 data reviews
- The performance of a primary proof reading by administrative support staff and a secondary proof reading by managerial staff of the compiled results
- Assurance that all qualifications and narrations are included in the compiled reports and are correct
- The data package is complete and ready for submittal to the client

Department of Defense Data Package Reviews:

The Quality Manager will review at least 10% of all Department of Defense data packages for technical completeness, accuracy, and DoD-QSM compliance. This review is part of the oversight program and does not have to be completed in "real time".

Validation Checks:

In the event of client or regulatory question of data, the following validation checks may be made:

- Method - check to be sure the method was appropriate and performed properly
- Calculations - check all calculations for data in question
- Standards and Titrants - check to determine if expiration dates were exceeded or standards were contaminated or prepared improperly
- Instruments - check instrument function and calibration data
- Transcription Error – check data for errors, dilution factors, etc.

Repeat Analysis - if the above investigation identifies any problems or fails to confirm the data, it may be necessary to repeat the analysis in question.

Data Reporting:

Specific data reporting responsibilities for analysts are provided in the SOP's.

For reports that are not generated through the LIMS, the analyst's bench sheets and raw data are reviewed by the Laboratory Area Manager and released to reporting.

For LIMS reports, the Laboratory Area Manager performs a batch review of the data in LIMS and the Project Manager, with assistance from administrative assistants, performs a work order review of the data before it is released to reporting.

After issuance of a report, the report must remain unchanged. If it is necessary to make changes to a report after it has been issued, it must be done so in the form of a further document, which is identified as a supplement to the original report.

Client Feedback:

TRACE actively seeks customer feedback in the form of client surveys, but any form of client feedback is addressed, however received. This is useful for TRACE's management to better understand our clients' needs and concerns and to make improvements to our overall operation. All customer correspondence with regard to complaints should be handled by the Project Manager. When necessary, these individuals can consult with the Laboratory Manager, Laboratory Area Managers, or QA/QC Manager to resolve and document complaints through the use of a non-conformance memo or other appropriate means. All correspondence must be documented on the client correspondence log or in the project file. Refer to section 14 for feedback on non-conforming work.

SECTION 13: Quality Control

There are a number of quality control tools employed by TRACE, in order to ensure that data are of satisfactory quality and within prescribed requirements for accuracy and precision. These tools and the minimum frequency of use are described below.

Blanks:

Blanks are artificial samples that are used to determine whether there has been contamination of samples, equipment or reagents. Analysis of a minimum of one blank sample per batch is required. There are several types of blank samples that may be analyzed. The types of blank samples to be employed for a particular project or analytical method may vary.

Field Blanks:

A sample of reagent water or sampling medium (*e.g.*, filter or absorption tube) that has been taken to the sampling site and exposed to the ambient air without exposing the material to sampling conditions. These samples will be used to determine the amount of background contamination that could arise from the sample being collected at the particular site.

Trip Blanks:

A sample of reagent water that accompanies a sampling crew to the sampling site and is carried back unopened to the laboratory under the same storage conditions as the actual samples. The purpose of these samples is to assess the potential for cross-contamination of volatile organics during sample shipment. A minimum of one trip blank per sampling event or per cooler is required by TRACE. Clients are encouraged to submit trip blanks as well.

Refrigeration Blanks:

A sample of reagent water or sampling medium (*e.g.*, filter or absorption tube, etc.) that is used to determine if there has been contamination of a cooler or refrigeration unit. These samples will be used to determine the amount of cross contamination that could arise from the samples being collected at the particular site.

Temperature Blanks:

Reagent water or other medium that is used to determine if the samples are being kept at the proper temperature during shipment.

Rinsate or Equipment Blanks:

A sample of clean water or solvent that is used to rinse equipment before or between samples to determine the potential for contamination from sampling equipment. The number of rinsate blanks to be submitted should be determined by the sampling crew based upon potential for cross-contamination at the site and whether disposable sampling equipment is being used, *i.e.*, no reuse of sampling equipment.

Reagent or Method Blanks:

A sample of reagent water or analytical medium (buffers, solvents, water with preservatives added, etc.) that is carried through the entire analytical process including sample preparation (extraction, digestion) and analysis. Frequency of these samples is a minimum of one per twenty or one per batch, whichever is more frequent.

Instrument Blanks:

A sample of reagent water or solvent that is analyzed between samples to assess the potential for cross-contamination in an analytical instrument or procedure. This sample is not carried through the sample preparation portion of the analytical method. The frequency of analysis of instrument blanks is variable and will be best determined by the analyst. For example, if a highly contaminated sample has been analyzed, instrument blanks will be analyzed until the analytical equipment fails to show any evidence of contamination. If a large number of samples that have no detectable contamination are analyzed, the necessity for instrument blanks is greatly reduced.

Spiked Samples:

Spiked samples are samples to which a known quantity of reagent or analyte has been added. Spiked samples are then analyzed to determine the performance of a method or analyst, or the stability of an analyte in the sample matrix. There are several types of spiked samples. These are usually analyzed at a minimum frequency of one spike per twenty samples or one per batch.

Laboratory Control Samples (BS):

Samples prepared by adding a known amount of analyte(s) to deionized reagent water, which are carried though the entire analytical procedure to assess the precision and accuracy of the procedure independent of sample matrix influence. Laboratory Control Samples (BS's) will be run with every batch of samples. Results will be within calculated control limits or those specified in the method.

Matrix Spike and Matrix Spike Duplicates (MS/MSD):

Samples that have a separate aliquot spiked with a predetermined quantity of analyte(s). The results of the MS/MSD's are used to assess the precision and accuracy of the analytical procedure when analyzing real world matrices. Results will be within calculated control limits or those specified in the method.

Duplicate Samples:

Samples are analyzed in duplicate to verify the precision of the analytical procedure.

Duplicates:

One sample prepared and analyzed twice in the laboratory. Duplicate analytical results are utilized to assess the precision of the analytical procedure.

Field Duplicates:

Replicate samples collected in the field or duplicate samples submitted by a client. These samples are analyzed and the results compared to assess the precision of the

entire sampling and analytical process. Duplicate analysis of one sample in the laboratory only tests the precision of the analytical procedure.

Surrogates:

Surrogate compounds are materials not usually expected to be found in environmental samples but are expected to behave similarly to an analyte of interest in the analytical process. Surrogates are often isotopic forms of environmentally significant materials.

These materials are added to a sample aliquot and carried through sample preparation and analysis. A satisfactory recovery of these materials demonstrates that the analytical process is in control.

Surrogate recoveries are calculated as follows:

$$SurrogateRecovery\,\% = \left(\frac{amount\,found}{amountspiked}\right) x100\%$$

Surrogates are added to all quantitative organic analyses.

Calibration:

All equipment, methods and procedures are to be calibrated prior to conducting analyses.

Calibration Standard:

A standard containing a known quantity of an analyte, which is used in conjunction with standards of other concentrations to determine instrument response (a standard curve). The number of calibration standards to be used is method dependent. The most common number of standards used to generate a response curve is five.

Calibration Check:

A standard containing a known quantity of an analyte, which has been purchased or prepared from a different source than the standards used to calibrate the equipment or method. These are used to verify the instrument calibration. These standards are not carried through the sample preparation portion of the analytical procedure. The normal frequency of analysis is defined in the appropriate SOP's. Some methods also require a calibration check prepared from the same source as the calibration standards.

Laboratory Water Quality:

The laboratory water quality is monitored on a regular basis. See SOP 10-21 for details.

Method Detection Limits (MDL) and Practical Quantitation Limits (PQL):

TRACE conducts MDL studies where applicable. In addition, MDL studies are performed each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis. At least seven reagent water samples and seven reagent soil samples are spiked at a concentration that is estimated to be the lowest level that can be reliably quantified. All processing steps of the

analytical method are included in the MDL determination. All procedures are documented, including the matrix, and all supporting data is retained.

The calculated MDL value is compared to the spike amount. The U.S.A.C.E. requires that the calculated MDL value be compared to the mean recovery of the spikes. If the calculated value is larger than the spiked amount, the MDL study is not valid and the procedure is repeated at a higher spike concentration. If the calculated MDL is between 100% and 20% of the spiked amount, the study is considered valid. If the calculated MDL is less than 20% of the spiked amount, the study should be repeated at a lower spike concentration.

MDL's refer to the minimum concentration of an analyte that can be detected above instrument background noise. On the other hand, Practical Quantitation Limits (PQL's) refer to a minimum concentration of an analyte that can be measured within specified limits of precision and accuracy. PQL's are generally 5-10 times the MDL, but no lower than 3 times the MDL. PQL's are established for each method and they must be above the detection limit.

Most methods do not have a frequency requirement for MDL studies. In these instances, annual or quarterly LOD and/or LOQ verifications are performed as dictated by our accrediting bodies. Those methods that require routine MDL studies will be noted in each individual SOP.

Limit of Detection (LOD) and Limit of Quantitation (LOQ) Verification:

TRACE conducts annual LOD and/or LOQ verifications for analytes certified through NELAC as required by The NELAC Institute Standard. The LODs and LOQs of DoD-ELAP accredited analytes are verified quarterly as required by the DoD Quality Systems Manual for Environmental Laboratories. Although these are referred to as LOD and LOQ in the laboratory, our LIMS system refers to these samples as MRL and SRM respectively due to naming limitations.

Employee Training and Initial Demonstration of Competency:

New employees are required to complete a number of tasks as part of their initial orientation. This includes QA/QC training, Data Integrity Training, Safety Training, a review of TRACE's Client Confidentiality Policy, and a review of TRACE's QA Manual. Prior to conducting the analysis of any client samples, all new analysts and technicians (trainees) receive training from the appropriate Laboratory Manager and must complete an Initial Demonstration of Competency (IDC). At a minimum, training will consist of a thorough study of the appropriate SOP's, instruction from the Laboratory Manager and performance of the analytical procedure(s) in tandem with the Laboratory Manager and/or Senior Analyst.

When, in the opinion of the Laboratory Manager, the trainee is capable of successfully conducting the analytical procedure, the trainee is required to complete the IDC, which consists of analyzing four BS's of identical concentration. The trainee must demonstrate the ability to obtain satisfactory precision and accuracy for the given procedure. The IDC data is reviewed by the Laboratory Manager and compared to the established control limits. If all values are determined to be in control, then the trainee is deemed capable to conduct the analytical procedure.

The results of the IDC will be documented in the employee's training file.

Additionally, the IDC may include satisfactory completion of a MDL study if the procedure will be utilized for drinking water samples, and generation of a curve with a correlation coefficient of >0.995 for procedures utilizing a curve for analyte quantification.

A demonstration of capability must be completed each time there is a significant change in equipment, personnel, or test method. Additionally, each analyst is required to conduct an on-going demonstration of capability on an annual basis. This is discussed in detail in Standard Operating Procedure 10-8.

Performance Evaluation Samples:

TRACE participates in several performance evaluation studies, including the USEPA Water Pollution (WP), Water Supply (WS), and Soil studies. These programs ensure that laboratory performance is checked and validated by an independent source on a regular basis. Once all analyses have been reviewed by the Laboratory Manager, or designee, the QA/QC Manager prints a final report of all results. The results are then entered online and submitted to the PT provider for evaluation. All records resulting from PT evaluations will be retained according to TRACE's record retention policy outlined in Section 5. Trace will comply with all TNI and DoD-ELAP requirements with regard to proficiency test studies.

SECTION 14: Corrective Actions

Corrective actions are required for two classes of problems: analytical or equipment problems and noncompliance problems. Analytical or equipment problems may occur during sample preparation, laboratory instrumental analysis, or data review. Non-compliance issues include, but are not limited to, sampling methodologies, sample containers, holding times, and sample preservation. This also includes any issues resulting from client feedback. In instances where a Corrective Action Report is necessary, the analysts and management will work together to determine the root-cause of the problem and determine corrective action. After an established timeframe, the QA/QC Manager will determine the effectiveness of the corrective action and determine if further action is needed.

The QA/QC Manager is responsible for informing management of deficiencies in the quality program and following up on corrective actions.

Analytical or Equipment Problems:

Corrective actions are required whenever an out-of-control event or potential out-of-control event is noted. The investigative action is dependent on the analysis and the event. Laboratory personnel are alerted that corrective actions are necessary if:

- BS and matrix spike data are outside the acceptable windows for precision and accuracy.
- Blanks contain target analytes above acceptable levels.
- Undesirable trends are detected in spike recoveries or relative percent difference between duplicates.
- Surrogates or internal standards fail QC criteria.
- There are unusual changes in detection limits.
- Deficiencies are detected by the QA/QC Manager during internal or external audits or from the results of performance evaluation samples.
- Inquiries concerning data quality are received from clients.

Resolutions:

Analytical Problems:

Corrective action procedures are often handled at the bench level by the analyst, who reviews the preparation or extraction procedure for possible errors, checks the instrument calibration, spike and calibration mixes, and instrument sensitivity. If the problem persists or cannot be identified, the matter is referred to the appropriate Laboratory Area Manager for further investigation. This investigation may involve the preparation of new samples, standards, reagents, and quality control spikes to determine the exact nature of the problem.

Once the problem is resolved, all samples affected by the problem must be reanalyzed.

If the problem is not resolved, a Corrective Action Report is completed with assistance from the analyst, Laboratory Area Manager, and QA/QC Manager. If client data is affected by the non-conformance, the Project Manager is informed. The affected data is qualified using the suitable qualifier from TRACE's Narrative list.

Inaccurate Procedures or Processes:

If it is determined that the problem causing the inaccuracy could have been prevented by following normal procedures or processes, actions will be taken by the QA/QC Manager or appropriate laboratory manager to inform or educate the analyst in an effort to prevent further occurrences of the problem.

Should the inaccuracy be due to an error, inconsistency, or ambiguity in a written procedure, the QA/QC Manager or Laboratory Manager will take all steps necessary to correct the problem. This corrective action may include rewriting the SOP.

Known departures from policies and procedures must be cleared by the Laboratory Manager and Project Manager. It is the Project Manager's responsibility to notify the client immediately to discuss these departures. Any known departures will be noted in the final report with a data qualifier.

Data Error:

Should an error be discovered in reported data, it is the policy of TRACE to immediately notify the client of the error by the most expeditious means. The analyses are repeated if necessary and the corrected results are reported as soon as possible. An amended written report will be prepared and will indicate the changed data and the reason for the change.

Resolution of Non-compliance Problems:

For non-compliance problems, a formal corrective action program will be determined and implemented at the time the problem is identified. At a minimum, a Corrective Action Report will be completed and the client notified immediately by the Project Manager for further instructions.

SECTION 15: Internal Quality Control Audits and Management Reviews

Internal quality control audits will be conducted at a minimum of once a year. The audits are conducted by the QA/QC Manager and President. The purpose of these audits is to verify that all aspects of the QA program, including data integrity, are functioning properly and that the overall quality program is effective. Two types of audits are used; system audits and technical audits.

System audits review the quality system, including information such as:

- Published methods
- Standard Operating Procedures
- Training files
- Quality control charts
- Quality control data
- Corrective action procedures and documentation

Technical audits are in depth reviews of data, with emphasis on data integrity issues. Technical audits involve a review of the following:

- Logbooks (Run logs and Standard prep. logs)
- Quantitation Reports
- Bench sheets
- Raw data
- Client reports
- Data review documentation
- Client correspondence
- Chain-of-Custody

Audit findings must be documented, and corrective actions established to address the findings. At the time that the corrective action is established, a mechanism must be defined to monitor the issue and ensure that the corrective action has been effective.

Management meetings will typically be held bi-weekly to discuss issues such as:

- The use of appropriate policies, procedures and standard operating procedures
- Employee reports/concerns/issues
- Internal audit findings
- Corrective/preventive actions
- External audit/review/assessment findings
- Proficiency test results
- Work schedules
- Client complaints/comments/concerns
- Quality control issues, resources, training, etc.

The President, Laboratory Manager, QA/QC Manager, Project Managers, and any Technical Managers will attend the bi-weekly meetings.